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09/840,730	04/23/2001	Michael R. Hufford	IVQ-003RCE	4534
21971 7590 01/29/2009 WILSON SONSINI GOODRICH & ROSATI 650 PAGE MILL ROAD PALO ALTO, CA 94304-1050				
EXAMINER				
OUELLETTE, JONATHAN P				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/840,730

Applicant(s)

HUFFORD ET AL.

Examiner

Jonathan Ouellette

Art Unit

3629

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-51 and 54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-51 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/02)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Claims 1-32, 52, 53 have been cancelled; therefore, Claims 33-51 and 54 are currently pending in application 09/840,730.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claims 33-41, 51, and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,362,440; Karidis et al. Flexible Interface Portable Computing Device. Hereinafter referred to as Karidis.**

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention

was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 33-41, 47-48, 51 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,362,440 Karidis et al. Hereinafter referred to as Karidis.**
6. As to **independent Claim 33**, Karidis teaches a method of detecting an event RELATED to data entry onto paper with an electronic instrument incorporated it diary (C15 L35-40) and capturing and storing CHARACTERISTICS of the related event (C10 L17-20); wherein said paper diary is a binder (Fig.1, C2 L66-67, C3 L1-19, Hinged Casing is equivalent to a binder; C7 L17-26, recording unit can incorporate paper); wherein said electronic instrument is incorporated into an outer casing of the paper diary and is hidden from view (Fig 11. 101, recording unit is in the Casing 208 and is hidden from the user under the paper forms 150); and wherein the electronic instrumentation includes a sensor for detecting when a subject uses the paper diary (C7-C8, Recording unit processor activates data retrieval once user begins use).
7. As to claims 34-37, Karidis teaches a system and apparatus with several options for sensors that detect use (C7 L51-53 & C14 L51-53).
8. As to claim 38-41, Karidis teaches time and date stamping a record when detection is made by recording unit (C10 L17-20).
9. As to **independent Claim 47**, Karidis teaches method of detecting an event RELATED to data entry onto paper with an electronic instrument incorporated it diary (C15 L35-40)

and capturing and storing CHARACTERISTICS of the related event (C10 L17-20); wherein said paper diary is a binder (Fig.1, C2 L66-67, C3 L1-19, Hinged Casing is equivalent to a binder; C7 L17-26, recording unit can incorporate paper); wherein said electronic instrument is incorporated into an outer casing of the paper diary and is hidden from view (Fig 11. 101, recording unit is in the Casing 208 and is hidden from the user under the paper forms 150); and wherein the electronic instrumentation includes a sensor for detecting when a subject uses the paper diary (C7-C8, Recording unit processor activates data retrieval once user begins use).

10. Karidis fails to teach the data that is being entered/recorded or tracked as clinical trial data.
11. However these differences are only found in the nonfunctional descriptive data and are not functionally involved in the steps recited. The data recording system/ method would be performed regardless of the type of data recorded or the possible use the collected data. Thus, this descriptive data will not distinguish the claimed invention from the prior art in terms of patentability, *see In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994).
12. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have entered/recorded or tracked clinical trial data, because such data does not functionally relate to the steps in the method claimed and because the subjective interpretation of the data does not patentably distinguish the claimed invention.
13. As to claim 48 Karidis teaches creating an electronic record (C10 L17-20).

14. As to **independent Claim 51**, Karidis teaches a system and apparatus with a paper form for recording data with an electronic instrument incorporated into a paper diary that generates a record regarding the use of the paper diary (form) (C13 L35-40; C8 L1-3); wherein said paper diary is a binder (Fig.1, C2 L66-67, C3 L1-19, Hinged Casing is equivalent to a binder; C7 L17-26, recording unit can incorporate paper); wherein said electronic instrument is incorporated into an outer casing of the paper diary and is hidden from view (Fig 11. 101, recording unit is in the Casing 208 and is hidden from the user under the paper forms 150); and wherein the electronic instrumentation includes a sensor for detecting when a subject uses the paper diary (C7-C8, Recording unit processor activates data retrieval once user begins use).
15. Karidis fails to teach the data that is being entered/recorded or tracked as clinical trial data.
16. However these differences are only found in the nonfunctional descriptive data and are not functionally involved in the steps recited. The data recording system/ method would be performed regardless of the type of data recorded or the possible use the collected data. Thus, this descriptive data will not distinguish the claimed invention from the prior art in terms of patentability, *see In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994).
17. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have entered/recorded or tracked clinical trial data, because such

data does not functionally relate to the steps in the method claimed and because the subjective interpretation of the data does not patentably distinguish the claimed invention.

18. As to claim 54, Karidis teaches time and date stamping a record when detection is made by recording unit (C10 L17-20).

19. Claims 42-46 and 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over

US Patent 6,362,440 Karidis as applied to claims 47-48 above, and further in view of Non-patent literature article "Diary keeping in asthma: comparison of written and electronic methods." Hyland, et al. Hereinafter referred to as Hyland.

20. As to **independent Claim 42 and Claims 49-50**, Karidis teaches detecting an event RELATED to data entry onto paper with an electronic instrument incorporated it diary (C15 L35-40) and capturing and storing CHARACTERISTICS of the related event (C10 L17-20); wherein said paper diary is a binder (Fig.1, C2 L66-67, C3 L1-19, Hinged Casing is equivalent to a binder; C7 L17-26, recording unit can incorporate paper); and wherein the electronic instrumentation includes a sensor for detecting when a subject uses the paper diary (C7-C8, Recording unit processor activates data retrieval once user begins use).

21. Karidis fails to teach the data that is being entered/recorded or tracked as clinical trial data.

22. However these differences are only found in the nonfunctional descriptive data and are not functionally involved in the steps recited. The data recording system/ method would

be performed regardless of the type of data recorded or the possible use the collected data. Thus, this descriptive data will not distinguish the claimed invention from the prior art in terms of patentability, *see In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994).

23. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have entered/recorded or tracked clinical trial data, because such data does not functionally relate to the steps in the method claimed and because the subjective interpretation of the data does not patentably distinguish the claimed invention.
24. Furthermore, Karidis fails to expressly teach comparing the electronic record with what the user wrote on paper.
25. Hyland teaches a comparison of electronic and pencil diaries (Abstract). It would have been obvious to one of ordinary skill in the art at the time of invention to combine Hyland with Karidis as the electronic time coded diary provides a more accurate quality review of data entry, but the paper form is more desirable, comfortable or normal to the user (See KSR [127 S Ct. at 1739] "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").
26. As to claims 43-44, Karidis teaches time and date stamping a record when detection is made by recording unit (C10 L17-20).
27. As to claims 45-46, Karidis teaches time and date stamping a record when detection is made by recording unit (C10 L17-20).

28. Karidis fails to teach validity of data based on time.
29. However, Hyland teaches validity of a diary being completed the actual day rather than in retrospect (Pg. 1 C2.). It would have been obvious to one of ordinary skill in the art at the time of invention to combine Hyland with Karidis to be able to determine accuracy of data (See KSR [127 S Ct. at 1739] “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”).

Response to Arguments

30. Applicant's arguments filed on 10/6/2008, with respect to Claims 33-41, 49-51, and 54, have been considered but are moot in view of the new ground(s) of rejection.
31. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
32. Applicant's arguments filed on 10/6/2008, with respect to Claims 42-48, have been considered but are not persuasive. The rejection will remain as FINAL, based on the cited prior art.
33. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

34. The Applicant is directed to the clarified rejection above in regards to submitted arguments
35. The Applicant is also reminded that the Applicant's disclosure for the teaching of the "paper diary" is not limited in what the structure can be. On page 7-8 the Applicant discloses "the invention is not limited to the illustrated paper diary for recording pain and can comprise any format used to record information related to any number of subjects. Furthermore, the invention is not limited to the illustrated loose-leaf three-ring binder 11, and can comprise any suitable arrangement for recording information such as legal pad, folder, file and the like." Therefore, the structure of Karidis' apparatus has equivalent means for performing in a manner as claimed by Applicant.

Conclusion

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan Ouellette whose telephone number is (571) 272-6807. The examiner can normally be reached on Monday through Thursday, 8am - 5:00pm.
37. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss can be reached on (571) 272-6812. The fax phone numbers for

the organization where this application or proceeding is assigned (571) 273-8300 for all official communications.

38. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Office of Initial Patent Examination whose telephone number is (571) 272-4000. Information regarding the status of an application may also be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

January 29, 2009

/Jonathan Ouellette/

Primary Examiner, Art Unit 3629